DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

December 24, 2002

WARNING LETTER NYK 2003-09

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

William M. Vargulick, Owner
William M. Vargulick Dairy Farm
35934 Cutler Road
Carthage, New York 13619

Dear Mr. Vargulick:

An investigation was conducted at your dairy farm by U.S. Food and Drug Administration (FDA) Investigator Bruce G. Cooper on September 16 & 19, 2002. The investigation confirmed that you offered a cow for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4), of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342, and that you caused an animal drug to become adulterated within the meaning of Section 501(a)(5) of the Act, 21 U.S.C. § 351.

On or about May 9, 2002 you sold a cow to [redacted] Before leaving your farm, this cow was identified with ear tag No. W836 by the trucker, [redacted] who hauled the animal. Upon arrival at [redacted] the cow was further identified with slaughter back tag No. 21NE7191. This cow was later delivered to and slaughtered at [redacted] on or about May 9, 2002. USDA analysis of tissue samples from that animal revealed the presence of the drug oxytetracycline in muscle tissue at a level of 3.22 ppm. This exceeds the 2.0 ppm tolerance identified in 21 CFR (Code of Federal Regulations) 556.500. The presence of oxytetracycline at this level in the muscle tissue of cattle causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

Our investigation found that you hold animals under conditions which are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack a system for assuring that drugs are used in a manner not contrary to label instructions, and for assuring animals medicated on your farm have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous drug residues from edible tissues. Food from animals held under such conditions is adulterated within the meaning of Section 402(a)(4) of the Act.

Our investigation also revealed that you caused a drug oxytetracycline hydrochloride injection (Agrimycin 100) to be unsafe within the meaning of Section 512 of the Act and adulterated under Section 501(a)(5) of the Act when you used the drug in an extralabel manner without veterinary supervision. This drug is indicated for use in non-lactating dairy cattle and for intravenous use only. Your use of this drug for treatment of mastitis by intramuscular injection or for treatment of a retained placenta by intrauterine injection in a lactating cow in an amount not indicated causes the drug to be unsafe to use.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, it is your responsibility to assure your operations are in compliance with the requirements of the Act. As a dairy farmer, you are the individual who introduces or offers for introduction into interstate commerce the adulterated food animals. It is not necessary for you to personally ship a food animal into interstate commerce to be responsible for violation of the Act. The fact that you caused the adulteration of a food animal that was sold and subsequently offered for sale to an auction barn and/or slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for violation of the Act.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to achieve prompt corrective action may result in regulatory action without further notice. This may include seizure and injunction.

Please notify this office in writing, within 15 working days, of the steps you have taken, or intend to take, to prevent a recurrence of these or similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made. Your written response should be directed to Patricia A. Clark, Compliance Officer, U.S. Food and Drug Administration, 300 Pearl Street, Suite 100, Buffalo, New York 14202, telephone 716-551-4461, ext. 3168.

Sincerely,

Jerome G. Woyshner
District Director